

# Independent Review Board

STATE OF WISCONSIN

## MINUTES OF THE MEETING OF MAY 21, 2004

### Attendance

**Board Members:** Chair Dr. Jay Gold; Vice-Chair Dr. Paul Millea; Eileen Mallow; and Dr. David Zimmerman. Absent: Jerry Popowski.

**Bureau of Health Information Staff:** Judith Nugent, Chief, Person-Level Data and Analysis Section; Audrey Nohel; Al Nettleton; Collene McHugh; and Susan Smith.

**Others Present:** Cindy Helstad, Wisconsin Medical Society; Jerry Hisgen, Meriter Hospital; and John Bott, Alliance Health Cooperative.

### Call to Order

At 10:05 a.m., Dr. Jay Gold called the meeting to order. A quorum was deemed present.

### Minutes of the March 26, 2004 meeting

Dr. David Zimmerman made a motion to approve the minutes, and Dr. Paul Millea seconded the motion. The motion passed, and the minutes were approved.

### Introductions and temporary change in staff

Dr. Gold reintroduced Collene McHugh as BHI staff to record the IRB meeting minutes. David Woldseth was unexpectedly absent due to the death of his father. Eileen Mallow made a motion to extend the IRB's condolences to Mr. Woldseth on his loss. Dr. Zimmerman seconded the motion, and the motion carried.

### Board on Health Care Information report

Since Jerry Popowski was unable to attend the meeting, Judith Nugent reported on what happened at the April BHCI meeting. Ms. Nugent reported on three items. First, the Board on Health Care Information discussed its evolving role under Chapter 153 after the privatization of the data collection. Second, they discussed physician office visit (POV) data. Third, Ms. Nugent reported that Secretary Helene Nelson was convening a meeting on Monday, May 24, to discuss an overall picture of how health care data, including POV data, are being used by the public and private sectors. Participants at the May 24 meeting will include the administrator of the Division of Health Care Financing, Mark Moody, the director of the Bureau of Health Information, Susan Wood, and outside advisors. Ms. Nugent stated that Susan Wood would update the IRB on this meeting at their July meeting.

Dr. Gold said he was concerned that the IRB, charged with developing policy for releasing POV data, was not invited to attend this May 24 meeting. He said that administrators may make decisions without any knowledge of the work, policies, and guidelines already set in motion. Ms. Nugent responded that she would express these concerns to the Secretary's Office after today's meeting.

Dr. Zimmerman said he hoped it was an oversight. Ms. Nugent did not have much of a part in organizing the Secretary's meeting, and she did not have direct knowledge of who was attending and who was not. Dr. Zimmerman made a motion, seconded by Dr. Millea, that Ms. Nugent express to the Division and to Mark Moody their concerns about not being notified or invited to the meeting.

The motion passed.

Dr. Millea asked about the privatization of data collection and how that affected the Board. Ms. Nugent told IRB that a large portion of the Board's responsibilities concerned oversight of this data. Also, the pending transfer of the Bureau of Health Information from the Division of Health Care Financing to the Division of Public Health and the Bureau's added policy responsibilities may also affect the Board's mission. In addition, two Board members, Chair Ron Dix and Vice-Chair Terri Potter, announced that they would not seek new terms after the expiration of their current terms, which ended May 1. The long-term leadership will now be gone. Neither the Board nor the staff knows anything about who will be chair, so BHCI currently operates in a state of flux.

Dr. Gold wondered about the broader issue of what the future role of BHCI would be, regardless of membership or leadership. BHCI may not have a voice in its own future. If BHCI does not, Dr. Gold asked Ms. Nugent if she knew who would decide that future. Ms. Nugent answered that BHCI is statutorily created, has statutory authority and responsibilities, and is appointed by the Governor. No changes have been proposed in any of these areas. The re-organized Division of Public Health will also include a new statutory board called the Public Health Council (PHC). The secretary will appoint 23 members to the PHC with the concurrence of the Governor.

The new Bureau of Health Information and Policy (which will succeed the Bureau of Health Information) will have at least three Board entities attached of interest: 1) BHCI, appointed by the Governor, 2) IRB, appointed by the Governor, and 3) PHC. Ms. Nugent has suggested overlapping appointments for better communication, but it is still unclear whether this will happen.

#### **Signing of Data Use Agreements (DUAs)**

Judith Nugent had believed BHI had received a data request that the IRB needed to consider at this meeting; however, the request changed, and it no longer involved sensitive, confidential data elements. Staff had contacted the DHFS Office of General Counsel to receive advice on closing meetings when necessary. BHI has another data request that may involve these data elements, but it has not yet been finalized. To prepare the IRB members for future meetings when meetings may need to be closed, Ms. Nugent requested each member and staff member sign a Data Use Agreement for POV data, and that was accomplished at this meeting. Susan Smith, a notary public, assisted IRB in this task. Jerry Popowski, who was absent, must yet sign a DUA.

#### **Physician Office Visit (POV) data request walkthrough**

Audrey Nohel, team leader for POV data, brought IRB up to date on the data and explained its rules of use. She distributed a handout of the team's objectives and talked about how they have been dissecting the language in administrative rules for handling customized data requests. She also talked about the need to develop status reports for customers, BHI managers, and the IRB. The team has had several meetings to interpret the rules and develop a business process flow chart. The team also has considered a number of hypothetical scenarios in lieu of actual data requests.

Ms. Nohel said the team identified three types of data elements: 1) public use data elements; 2) patient identifiable data elements; and 3) "IRB territory" data elements. The POV dataset can be merged with other datasets within DHFS such as the physician workforce survey that contains physician license numbers. The IRB review process must include these considerations since the effects are not limited simply to POV data. DHFS has also created a draft application form for the data that Ms. Nohel distributed. It asks type of data and type of business.

Administrative rules (Chapter 120) require that BHI provide an information packet to data customers that has four components: data request specifics, cost estimate, fees to be collected in advance, and a prepared tangible sample for review. DHFS intends to include all these steps and decision processes in a business process analysis flowchart and in a data request tracking system that should be in place in June. The data request process will be more complicated than other BHI processes have been in

the past. Ms. Nohel also pointed out there will be a lag time on data requests between the date of the request and the IRB meeting dates.

Ms. Nugent asked IRB members to look at Section 3 of the handout to give feedback. Dr. Millea had several initial comments about the information regarding a principal investigator, data access, data sharing plans, and assurances that the data will not be used for other purposes. He also shared his belief that storage and security will be issues. Al Nettleton stated BHI voluntarily follows HIPAA privacy requirements.

Dr. Millea pointed out that data might be redisclosed without permission under HIPAA. Dr. Gold responded that the BHI data use agreement does not permit redisclosure so there is more protection than under HIPAA. Ms. Nugent talked about how the whole process is still in the brainstorming and conception phases. She also reported that BHI recently received a phone call regarding the process, which has given the issue more urgency.

Ms. Nugent reported that her office has received a data request from Chiron, one of the two companies in the United States that provides flu vaccines. The request would help Chiron since the company does not want the previous vaccine shortage to recur. The possibility of using POV data excited Chiron. They want aggregate data and the data broken out by clinic, age, and gender. DHFS must yet decide how much to charge for this request.

Dr. Gold said he appreciated that Ms. Nugent kept IRB informed, and it sounds like there may be a public health rationale to this request. Dr. Millea asked what else would be done with the information since he wondered why they would want clinic-specific data.

IRB members discussed the possible marketing ramifications of the data request and of all data requests, and they weighed these against public health issues. They also had some legal questions about whether they could or should even consider marketing ramifications or ask what users plan to do with the data. Dr. Zimmerman made a motion asking staff members to review legislative authority and any other regulatory discussions there has been and determine whether these issues fall within the purview of IRB. Dr. Gold seconded the motion.

Dr. Zimmerman wondered if this was an issue on which the Division of Public Health needs to act. Ms. Nugent clarified that this particular data request asks only for what is already in the public use dataset. Chiron could technically do the analysis on their own, but they asked BHI analysts to do it for them for a fee. Dr. Millea believed DHFS should simply sell them the data and let them do the rest.

Dr. Gold called the question. The motion read: "Staff should review legislative authority to determine whether or not marketing and data issues fall within the IRB purview." The motion passed.

Dr. Millea asked about marketing to flu vaccine companies. Ms. Nugent stated the new Bureau director, Susan Wood, is very interested in addressing the financial difficulties of the Bureau and the Division by marketing data. However, she awaits the advice of the Secretary's Office before BHI would act on this.

Dr. Zimmerman thought Dr. Millea's question was whether DHFS has a responsibility to offer the data to others as well when competitors of a data requestor ask. Dr. Millea also asked about cost standards for customized data when the request has already been filled. Ms. Nugent answered that the second requestor would be charged the same as the initial requestor even though much of the investigative work had already been done, and the request would, in reality, be less expensive for the agency.

Ms. Nugent then reported that BHI has received a data request from the University of Wisconsin Comprehensive Cancer Center. It wants to identify oncology codes in the POV datasets and to flag codes also in the Tumor Registry. There are many statutory issues, so this may come back to IRB as

a data request at a future meeting.

IRB members speculated about various data linkages and how IRB would respond to those requests that affect them. Dr. Gold believes that, as IRB receives more specific information, it will be better equipped to have those discussions. Dr. Zimmerman reiterated that the issue to him is whether any of this is the IRB's business. A narrow definition of statute only protects the identity and preserves the confidentiality of the information. However, there are certainly stakeholders who would benefit from a wider definition.

### **Release of physician identifiers**

Judith Nugent reported that BHI is very close to releasing public use data for the 4<sup>th</sup> quarter of 2003. That will mean that four quarters of public use POV data have been released. Users have commented on how to improve the data. Consistently, customers request physician identifiers, so they can perform the types of analyses they would find most useful.

At the last meeting, IRB requested that staff write a position paper that provides reasons to release or not to release physician identifiers. Richard Miller, a BHI analyst who was unable to attend the meeting, believes strongly that datasets should include both physician license numbers and ZIP codes. By statute, IRB could approve both these additions to the public use dataset. Al Nettleton and Ms. Nugent developed reasons IRB should not. In either event, BHI and IRB would continue to need to protect confidentiality by not releasing small data cells.

Dr. Zimmerman suggested IRB discuss this at its next meeting after reviewing and studying the information. Also, at that time, members and outside interests may speak about the benefits and disadvantages of releasing physician identifiers.

Ms. Nugent pointed out that when BHI markets the POV public use dataset, it will need to price it. Customers report that, without the physician identifiers, the data will not have enough utility that they would choose to buy it. IRB must determine whether these identifiers will be included only in customized data requests or in the public use datasets as well. Dr. Zimmerman asked staff to extract excerpts from the statutes with respect to language about the IRB's authority in this regard. Also, since these are open meetings, he suggests that we allow other stakeholders to state their case and to make sure that people understand the next meeting will be the one where this will be discussed and debated in great detail.

The next meeting may attract more attention than previous meetings have. Therefore, IRB may need a larger room for its next meeting. Dr. Gold said he hopes the process will be deliberative and non-confrontational. Dr. Millea added that he hopes this issue will not polarize people and that IRB can reach consensus. Ms. Nugent reminded IRB it has the option of using pseudo-license numbers, so users can look at a particular physician without knowing which one. There was some concern expressed that this solution would be unsatisfactory and would satisfy no one.

### **Potential items for upcoming IRB meeting**

- Update on the May 24 meeting;
- Discussion of physician identifiers; and
- Discussion of the role of BHI/IRB in marketing data.

### **Other POV issues**

Judith Nugent noted that an IRB member asked at a prior meeting about the definition of a POV visit. For the data, it has been defined as, "All of the service records associated with the same physician and the same patient on the same day."

Al Nettleton said that about 4,200 physicians per quarter are currently represented in the datasets. The size of the entire pool of physicians cannot be easily ascertained. DHFS uses 12,000 as the rule

of thumb, but there are 18,000 physicians with active Wisconsin licenses. Phase 2 of the data collection will occur after July 1. After that date, more clinics may be added to the data collection requirement. According to Mr. Nettleton, Phase 2 should double the number of physicians in the dataset.

#### **Next IRB meeting**

The next meeting has been scheduled for July 16, 2004, 10:00 a.m. to 12:00 p.m., at the State Office Building, One West Wilson Street, Conference Room 372, Madison, Wisconsin. However, staff has been directed to find another, larger location since the debate over physician identifiers may attract more interest.

#### **Adjournment**

Dr. Gold adjourned the meeting at 11:48 a.m.